UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEY'S OPPOSITION TO UNITED STATES' MOTION TO EXCLUDE CERTAIN OPINIONS OF W. DAVID BRADFORD, PH.D.

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") hereby submit their opposition to the United States' Motion to Exclude Certain Opinions of W. David Bradford, Ph.D. In their memoranda, Dkt. 6914 ("DOJ Brief"), the United States ("DOJ") does not challenge Dr. Bradford's qualifications as an expert nor do they seek to exclude all of his testimony. Instead, the DOJ argues that certain portions of Dr. Bradford's Medicare and Medicaid opinions should be excluded. They make no argument as to the admissibility of almost two-thirds of Dr. Bradford's report and appendices. Dr. Bradford will testify at trial regardless of the outcome of the DOJ's motion, and the issues raised by the DOJ at most identify areas for cross-examination at trial.

The strategic reason for the DOJ's motion is easily apparent when one realizes the DOJ does not have an expert who can rebut Dr. Bradford's opinions because they have not designated the equivalent of Dr. Raymond Hartman, who testified in the MDL trial as to the relationship between AWP and WAC in the context of brand drugs, but whose analysis did not apply to

generics.[1] Dr. Bradford is a health care economist with unchallenged qualifications and his testimony will be helpful to the Court and the jury in explaining the economics of generics. In addition, Dr. Bradford has done that which *no* other expert, including the DOJ's, has done in any of the three cases brought by the DOJ: he has actually analyzed the state level claims data and can testify to actual error rates, as opposed to hypothetical error rates, as well as to the effects of missing data. The Government does not challenge these opinions on this motion. Instead, it tries to prevent testimony which goes to the heart of this case - testimony concerning dispensing costs for inhalation drugs, for example - by essentially asserting that Dr. Bradford is offering "legal" opinions or that certain isolated portions of his report are "misleading." The latter is a point for cross-examination, and the former is demonstrably untrue when the report is looked at as a whole. As a whole, the report examines the key issues the DOJ's experts studiously avoided: the reality of generic competition, the dispensing cost issues and the observed behavior of CMS and state Medicaid agencies which show that the "but for" prices for ingredient costs for Dey's inhalation drugs used by the DOJ's expert, Dr. Duggan, were unlikely to have been used in reimbursement formulas absent large dispensing fee increases. In short, the DOJ seeks to exclude expert testimony from a qualified expert on the very issues this Court has found in the past to be centrally relevant.

BACKGROUND

Dey's expert, W. David Bradford, Ph.D., is the Busbee Chair in Public Policy in the Department of Public Administration and Policy at the University of Georgia. He was formerly

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[1] *See* Hartman Texas 7/23/09 Dep. at 430:15-432:16, Reid Decl. Exhibit 1 (stating that for generics, "[t]he WACs I've followed less closely in what their patterns are" and that he has not studied generic WACs closely enough to comment on their relationship with transactional prices); see also *In re Pharmaceutical Industry Average Wholesale Pricing*, 491 F. Supp. 2d 20, 86 (D. Mass. 2007) (discussing that Dr. Hartman only uses his 30% yardstick for single-source drugs and for six months after the first generic launch).

the Director and founder of the Center for Health Economic and Policy Studies at the Medical University of South Carolina and has been a visiting faculty member at Yale Medical School and a tenured faculty member in the Department of Economics at the University of New Hampshire. He has over 17 years of research in the area of health economics in general, with a focus on the role of incentives and regulations on economic efficiency. He has been the principal investigator on 15 funded grants and projects, including several which have focused on the functioning of various components of Medicaid and which involved directly working with Medicaid personnel. Dr. Bradford has published 45 articles in peer-reviewed publications and has authored numerous other reports and publications. Dr. Bradford is co-editor of the peer-reviewed journal *Health Economics Letters.* He is also on the editorial board for the journal *Health Economics*, serves on the editorial board of the newsletter of the American Society of Health Economists, and is on the oversight boards for both the American Health Economics Conference and the Southeastern Health Economics Study Group.[2] The DOJ has not challenged the qualifications of Dr. Bradford in their motion.

In preparation for issuing his opinions in this case, Dr. Bradford reviewed an enormous amount of data and other information. In the Medicaid context, Dr. Bradford performed a careful and thorough analysis of all of the available state-level claims data, which included data for thirty states[3], the SDUD data and SMRF/MAX data for all fifty states and Washington, D.C.,

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[2] The DOJ filed Dr. Bradford's report in connection with their motion, as Exhibit 1 to Dkt. 6194. A full copy of Dr. Bradford's curriculum vitae is attached to his report as Appendix A. A courtesy color copy of Dr. Bradford's report and appendix is being filed with the Court.

[3] Dr. Bradford reviewed and analyzed claims data from the following states: Alaska, Alabama, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Massachusetts, Maine, Michigan, Minnesota, Missouri, North Carolina, Nebraska, New Mexico, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, Utah, Virginia, and Wisconsin.

wholesaler data from Cardinal and McKesson, pricing data from three compendia, transactional data from Dey, AMP data, and other pricing information relating to the ingredient and dispensing costs of the Dey subject drugs.[4] In addition, Dr. Bradford reviewed and relied upon numerous documents and testimony that are a part of the record in this case in formulating his Medicaid opinions. In the Medicare context, Dr. Bradford carefully studied the Medicare claims data, the Medicare arrays, studies on the cost of dispensing inhalation drugs used with a nebulizer, and other testimony and evidence as to the costs for inhalation drugs in particular as well as their role within the Medicare program.

In addition, Dr. Bradford reviewed the calculations of Plaintiffs' expert, Dr. Duggan, and formulated opinions as to Dr. Duggan's methodology and damages calculations for both Medicaid and Medicare. Dr. Bradford's review of Plaintiffs' damage calculations included detailed calculations of error rates derived from the actual claims data for Dr. Duggan's Medicaid extrapolations. *See, e.g.,* Bradford Decl. at Ex. C. Unlike Dr. Duggan, who calculated an alternative average price for ingredient cost without considering or studying the literature which demonstrates that any Medicare or Medicaid reimbursement is based on more than just ingredient cost, Dr. Bradford reviewed the data and documents in order to further his understanding of the various factors that impact pharmacy reimbursement and that are considered by these programs. Dr. Bradford also addressed errors made in Dr. Duggan's Medicare calculations (*see, e.g.*, ¶¶ 305-311), which Dr. Duggan found reliable enough to adopt in subsequent reports, reducing the amount of damages claimed by the DOJ. Dr. Bradford's extensive review of data and information in this case, coupled with his experience and expertise in health-care economics, generics and reimbursement, culminate in his substantial report and

[4] A complete list of materials and data considered by Dr. Bradford is located in Appendix B to his expert report. Dkt. 6194 at Ex. 1.

many pages of supporting appendices. *See* Dkt. 6194 at Exhibit 1. Since the submission of his report, Dr. Bradford has also submitted the following in response to further submissions by Dr. Duggan: a rebuttal report, dated May 7, 2009; a letter responding to Dr. Duggan's November 30, 2009 submission which set forth Dr. Duggan's purported "error" rates for his extrapolation, dated January 15, 2010, and a letter responding to Dr. Duggan's submission of confidence intervals, dated March 17, 2010. *See* Declaration of Dr. Bradford submitted concurrently with this response, at Exhibits A, B, and C. Dr. Bradford has also submitted two declarations in connection with the pending summary judgment motions, Dkt. 6180 and Dkt. 6426, Exhibit 405.

At this time, when the contours of the trial have yet to be determined, it is not possible for Dey to determine which of Dr. Bradford's opinions it will choose to present at trial. If this trial is limited, many of Dr. Bradford's opinions will not be presented.[5] Furthermore, certain opinions may not be proferred depending on how Plaintiffs present their case. Therefore, in addition to denying the DOJ's motion on the merits, judicial economy and efficiency also weigh in favor of denying the motion because it is premature and may well be unnecessary for this Court to decide.

ARGUMENT

I. LEGAL STANDARD

Rule 702 provides that expert testimony is admissible if "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702. The DOJ raises three main arguments why certain portions of Dr. Bradford's opinions should be excluded at the motion in limine stage. The DOJ argues that certain

[5] It has been Dey's consistent position that the DOJ's motion to consolidate should be denied and that the Medicare and Medicaid claims against Dey should be tried together. *See* Dkts. 6635 and 6767.

paragraphs of the report, generally taken out of context, are not relevant, characterizes certain opinions as impermissible "legal" opinions, and then selects a few paragraphs or figures and labels them "unreliable" or "misleading." At base, however, the DOJ has not demonstrated that any of the challenged Dr. Bradford testimony is inadmissible under Fed. R. Evid. 702.

Dr. Bradford's opinions are indisputably relevant to this case. Under the liberal standard applied to relevance, relevant testimony includes "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 587 (1993). Furthermore, "expert testimony must be relevant . . . in the incremental sense that the expert's proposed opinion, if admitted, likely would assist the trier of fact to understand or determine a fact in issue." *First Marblehead Corp. v. House*, 541 F.3d 36, 42 (1st Cir. 2008) (internal citation omitted).

The DOJ has alleged that "Dey has engaged in a fraudulent scheme that has caused the Medicare and Medicaid programs to pay excessive reimbursement to Dey's customers" by reporting inflated prices to the compendia. The DOJ's expert, Dr. Duggan, has calculated average prices that purport to be the prices which Dey should have reported and the Government would have paid for the Dey subject drugs without doing any study as to the feasibility of using those prices beyond his arithmetic exercise. In contrast, Dr. Bradford performs that study. Dr. Bradford's report does not offer opinions that go beyond the kinds of opinions this Court has previously permitted. Dr. Bradford's opinions on Medicaid and Medicare dispensing fees and cross-subsidization, his opinions about Dey's use of a transactional, reported WAC, and his other challenged opinions are all relevant because they will assist the jury in evaluating the observed economic behavior by the participants during the relevant time frame, which in turn bears

critically on whether this defendant caused, or could have believed it was causing, the programs to overpay providers such as home health care providers or pharmacies for dispensing the subject drugs. Such an exercise will not be possible for the jury without the assistance of expert testimony.

Furthermore, the challenged opinions of Dr. Bradford are not impermissible legal opinions. Courts will allow "testimony from expert witnesses that shed light on activities not within the common knowledge of the average juror." *See, e.g.*, *United States v. Duncan*, 42 F.3d 97, 102 (2d Cir. 1994) (permitting questioning regarding the proper functioning of the tax system and the importance of filing tax returns because they "did not ask the witness to express legal conclusions, but only to explain sophisticated aspects of a regulatory system for which the witness had expertise"). [6] Here, Dr. Bradford's testimony regarding the Medicare and Medicaid framework is both necessary and helpful to the jury, and is also the type of evidence that this

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[6] The DOJ relies on *United States v. Newman*, 49 F.3d 1 (1st Cir. 1995) for their proposition that certain of Dr. Bradford's opinions should be excluded as legal opinions. This reliance on *Newman* is misplaced, because, in that criminal case, the statements in question opined as to the wrongful conduct of the defendant, and the Court found there to be no plain error in their admission. The court went on to state that "the general concern with statements of ultimate legal opinions is that juries may be confused or may accept the offered opinions in lieu of the legal rulings of the judge." *Id.* at 7. Here, the opinions of Dr. Bradford that are challenged by the DOJ go to the complex framework of Medicaid and Medicare and not the ultimate question of whether Dey's conduct is actionable under the False Claims Act. These opinions should therefore be allowed to be presented at trial. In the other case cited by the DOJ, *Marx & Co. Inc. v. Diners' Club, Inc.*, 550 F.2d 505, 512 (2d Cir. 1977), a securities case, while the court found that the expert's conclusions of law in construing the parties' contract were improperly admitted, the court also described the situations when the expert could offer opinion, including that "the expert, for example, may tell the jury whether he thinks the method of trading was normal, but not, in our view, whether it amounted to illegal manipulation under Section 9 of the Securities Exchange Act . . . He may explain the nature of an option contract, or of a convertible preferred stock, but we doubt that he should be allowed to testify that under an option agreement one party or the other has acted unlawfully, or that a corporation should be held liable because through a recapitalization it changed the conversion ratio and that this was a breach of contract." Dr. Bradford is a health-care economist, not a lawyer, and his opinions do not purport to address the ultimate legal issue of liability.

Court has previously found to be admissible. For example, in the Class Action trial before this Court, plaintiff's expert Raymond Hartman was permitted to testify on some of the same type of issues that the DOJ seeks to exclude as legal opinion here. For example, Dr. Hartman opined that Medicare is "generally originally formally designed to be cost-based" and as well gave interpretations of CMS's actions and interpretations of various laws. (11/20/2006 Trial Testimony at 13:4-15; 15:12-16:24, Reid Decl. Exhibit 2).

The arguments raised by the DOJ are more properly addressed during cross-examination at trial. As the First Circuit has held: "[t]he burden is on opposing counsel through cross-examination to explore and expose any weaknesses in the underpinnings of the expert's opinion." *Int'l Adhesive Coating Co., Inc. v. Bolton Emerson Int'l, Inc.*, 851 F.2d 540, 544 (1st Cir. 1988). The court in *Int'l Adhesive Coating Co.* further held that in the event that "the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony -- a question to be resolved by the jury" and ultimately found the expert's testimony was properly admitted. *Id.* at 545. *See also United States v. Mooney*, 315 F.3d 54, 63 (1st Cir. 2002). Furthermore,

> As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process -- competing expert testimony and active cross-examination -- rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.

Ruiz-Troche v. Pepsi, 161 F.3d 77, 85 (1st Cir. 1998) (internal citations omitted) (reversing district court's decision to exclude expert testimony, vacating judgment, and remanding).

II. DR. BRADFORD'S MEDICARE OPINIONS ARE ADMISSIBLE

In its motion, the DOJ challenges three of Dr. Bradford's Medicare opinions. The DOJ does not challenge Dr. Bradford's qualifications in setting forth his opinions, the data used by

Dr. Bradford or his application of the data. Indeed, Dr. Duggan has accepted Dr. Bradford's observation of mathematical errors in his Medicare calculations. This Court should not exclude the Medicare opinion highlighted by the DOJ because it goes to a key issue in this case, one this Court has identified as such, and is a reliable economic opinion that will assist the jury. That issue is the issue of inhalation drug dispensing costs in the Medicare context. While the DOJ would like to pretend that the dispensing cost issue does not exist, it cannot escape the fact that Congress did consider it and acted on it. It is an issue that is raised by the DOJ's central allegation that Medicare and Medicaid "overpaid." That is important information for this trial and Dr. Bradford is well qualified to discuss it.

A. Dr. Bradford's Opinions Regarding Medicare Cross-Subsidization Are Relevant, Reliable, and Admissible

While the DOJ would like to exclude Dr. Bradford's comparison of subject drug prices before and after the Medicare Modernization Act ("MMA") and Dr. Bradford's discussion of Medicare dispensing fee shortfalls, (DOJ Brief at 8, 9), Dr. Bradford's opinions regarding Medicare dispensing fees are based upon sufficient facts or data, are the product of reliable principles and methods, and reliably apply the principles and methods to the facts of this case.

An allegation of overpayment cannot be presented to the jury without corresponding evidence of all of the elements of payment, including the dispensing fee. In fact, the opinions proffered by Dr. Bradford which are challenged by the DOJ answer the precise questions already raised by this Court. At the summary judgment hearing, this Court specifically asked "Would the extent of the spread end up in, you know, like $100 for a dispensing fee when the only reasonable one would be $33? Has anyone done the math or any expert looked at it?" (October 20, 2009 Hearing Tr. at 67:21-24). Dey subsequently filed a notice attaching four reports that

studied the dispensing cost for inhalation drugs.[7] (See Dkt. 6618). These reports outline the costs of dispensing inhalation drugs, the specific drugs that are at issue in this case. The opinions offered by Dr. Bradford specifically relate to those reports and to the increased dispensing fee enacted after the switch to ASP-based reimbursement.

The DOJ characterizes Dr. Bradford's study of dispensing fees as a legal opinion in an attempt to exclude these opinions. In arguing that Dr. Bradford's calculations "are premised on the false legal assumption that Dey's pre-MMA liability for damages should be measured by reference to post-MMA law" (DOJ brief at 10), the DOJ is misconstruing Dr. Bradford's point.[8] It is Dr. Bradford's opinion that "[i]t is simply not correct to assume, as Plaintiffs' experts do, that Medicare could have paid substantially less to home health providers for the subject drugs given the unrealistically low dispensing fees they received." (Bradford Rpt. at ¶ 240). The MMA ASP methodology is similar to the average prices calculated by Dr. Duggan. And, when reimbursement is based a lower price, such as ASP or Dr. Duggan's average prices, it is necessary to increase the total reimbursement to providers by increasing the dispensing fee. It is not possible to subtract from the ingredient side without adding something to compensate for an inadequate $5 dispensing fee. The actual cost of dispensing these drugs had exceeded $5 prior to the MMA, but once the ingredient cost reimbursement decreased and the inadequate dispensing

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[7] The reports were: an August, 2004 Muse & Associates study entitled, "The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries;" an October, 2004 report from the United States Government Accountability Office entitled, "Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs; " the Prepared Witness Testimony of Thomas Connaughton to the Committee on Energy and Commerce, dated September 21, 2001, entitled "Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers;" and a Lewin Group report, "Impact of Proposed AWP Reductions on the Provision of Home Drug Therapies to Medicare and Medicaid Patients," dated September 8, 2000.

[8] The DOJ refers to Appendix G of Dr. Bradford's report, but the correct citation is Appendix H.

fee was no longer covered by cross-subsidization, it was necessary to increase the dispensing fee to account for the loss. This tenuous equilibrium between the ingredient cost and dispensing fee exists regardless of the MMA. However, the MMA provides concrete evidence of the relationship between ingredient costs and dispensing fees in the inhalation drug context. As Dr. Bradford notes, the 2004 GAO study on dispensing fees for Medicare found that the per patient cost of dispensing ranged from $7 to $204, and the suppliers surveyed for the study explained that they "received drug payments substantially higher than their acquisition costs. Suppliers indicated that they used these excess payments to offer services that benefited both beneficiaries and their physicians . . ." (Bradford Rpt. at ¶ 239).

The DOJ also challenges the reliability of these particular opinions by interjecting the issue of whether the prices of all manufacturers in addition to Dey would need to be considered in order for the calculation of the dispensing costs to be reliable. (DOJ Brief at 11). This argument is a red herring; Dr. Bradford is simply critiquing Dr. Duggan's methodology and the implicit assumptions made by Dr. Duggan in holding all factors, such as dispensing fees, constant – implicit assumptions made without any consideration or study by Dr. Duggan. It is inconsistent for the DOJ to fault Dr. Bradford for performing analyses that critique Dr. Duggan's calculations on their face.

The DOJ has challenged several figures provided by Dr. Bradford which demonstrate the change in reimbursement levels. (DOJ Brief at 8). They critique the charts as misleading because the charts depict prices in the transition years of 2004 and 2005. The DOJ does not challenge that the charts accurately depict the prices in those transition years, but claim they should not be used at all. This is an issue that is properly left for cross-examination, where Dr. Bradford can be questioned about his choices. As it stands, there is nothing incorrect about the

charts. Furthermore, because the GAO study showed that in some instances the dispensing costs could be as high as over $200, Dr. Bradford's charts are actually conservative. The DOJ also claims that the chart depicting payment for cromolyn sodium is irrelevant, yet cromolyn sodium is a subject drug and the DOJ has not stated that it will not seek penalties for cromolyn sodium. The DOJ's lack of damage calculations for the drug does not render the chart inadmissible, should Dr. Bradford even decide to present it at trial. Finally, the DOJ challenges Figure 34 based on the inclusion of the J-Code J7616 which the DOJ claims is not relevant here because it does not apply to the subject drugs. This is not a reason to exclude the chart, because, as Dr. Bradford points out in his report, there was an off-setting pattern of utilization due to the introduction of the new J-Code J7616. Examining this type of behavioral response to policy changes is the province of a health care economist, and a relevant analysis for an economics expert.

B. Dr. Bradford's Medicare Opinions Regarding His Analysis of Dey's WAC Are Relevant, Reliable, and Admissible

This Court should not exclude Dr. Bradford's opinions regarding Dey's declining WAC in the Medicare context, identified by the DOJ as contained in paragraphs 248 and 312 of Dr. Bradford's report. (DOJ Brief at 7). Dr. Bradford has carefully reviewed Dey's published prices, the pricing of competitors, the function of those prices in the pharmaceutical industry, Medicaid and Medicare reimbursement policies, as well as numerous other sources in reaching his opinion. Over 20 pages of Dr. Bradford's report relate to Dey's declining WAC and are not included by the DOJ in their motion *in limine*. (*See*, *e.g.*, Bradford Rpt. at pages 16-37). Dey reported its AWPs and its declining WACs for the subject drugs throughout the time period at issue. As shown elsewhere in Dr. Bradford's report, and as unchallenged by the DOJ in their motion *in limine*, Dey's WAC functions as Dey's invoice price, is the price at which wholesalers

take title to Dey's drugs, and many of Dey's sales to off-contract providers take place above Dey's WAC. (Bradford Rpt. at ¶¶ 40-46). Dr. Bradford opines that Dey's WAC has a meaningful relationship with transaction prices, and the DOJ has not moved to exclude these opinions. (Bradford Rpt. at ¶¶ 53-66). The unchallenged figures charting Dey's AWP and WAC provided by Dr. Bradford demonstrate that Dey's WAC for the subject drugs is lower than AWP for those same drugs. (Bradford Rpt., Appendix C, *cf.* Figures 1-6 and 7-12). Nor does the DOJ critique Dr. Bradford's opinion that states which used Dey's WAC for Medicaid reimbursement had lower costs than those which chose to use AWP as a reimbursement basis. (Bradford Rpt. at ¶ 55). Indeed, the AWP calculated by Dr. Duggan which is 125% of his average prices[9] is very close to Dey's published WAC.

The only opinion relating to WAC that the DOJ seeks to exclude is Dr. Bradford's calculations which adjust Dr. Duggan's Medicare difference calculations by substituting Dey's WAC, the published price very close to what Dr. Duggan now claims Dey should have reported. (*Id.* at ¶ 312). The DOJ challenges the significance of this calculation, and not the actual calculation itself. They do not allege that he has improperly implemented Dr. Duggan's formula, that he has used incorrect arrays, or that he has used the wrong WAC price. Instead, they challenge the rationale behind the calculation. However, this opinion is admissible and it should be presented to the jury so that it may decide what weight to give to it. *See, e.g., Ruiz-Troche*, 161 F3d at 85. Dey's WAC was available from the same publications that contained Dey's AWP. Robert Vito testified that the OIG had recommended that Medicare use WAC. (*See, e.g.*, Vito 2/6/08 Dep. at 1053:17-1054:7, Reid Decl. Exhibit 3). Dr. Bradford accepts the law as given. His point is an economic one directed towards the existence of other known pricing

[9] Dey does not believe there is any rational basis Dr. Duggan has offered for marking up his average prices by 25% in order to generate his AWP.

points. The False Claims Act involves the element of scienter, and the fact that Dey was reporting two prices, one a flat AWP and one a declining WAC, to the compendia has clear bearing on that issue. A jury could find that Dey did not have the requisite intent to cause a "false claim" to be reimbursed by Medicare when it was simultaneously reporting another published price which would result in little to no alleged damages because it tracks Dr. Duggan's after-the-fact 125% average price.

C. Dr. Bradford's Opinions Regarding Dey's Medicare Sales May be Relevant, Depending on the Outcome of Pending Motions

Finally, the Court should reject the DOJ's relevancy challenges to Dr. Bradford's opinion regarding the connection between Plaintiffs' claims and Dey's actual sales contained in paragraph 258 and Appendix H.2. After reviewing the Medicare claims data and the Dey transaction data, Dr. Bradford opines that only a portion of the DMERC expenditures can be attributed to Dey's sales, which is not particularly controversial. (Bradford Rpt. at ¶ 258). The DOJ does not challenge the reliability of the data evaluated by Dr. Bradford, his methods, or his application of those methods for this calculation. Instead, the DOJ argues that this testimony is irrelevant under the False Claims Act. First, the DOJ's cite to this Court's New York FUL decision, which was not decided under the False Claims Act, is cited completely out of context and has no bearing whatsoever on this issue. Second, in the context of the joint scenarios, the DOJ's expert, Dr. Duggan, has examined market share in the Medicaid context and applied it to allocate Medicare damages. Here, Dr. Bradford has examined the actual Dey sales data in connection with the arrays. Depending on the Court's ruling on several outstanding issues, this data, and accompanying opinion, could be relevant and helpful to the jury.

III. DR. BRADFORD'S MEDICAID OPINIONS ARE ADMISSIBLE

The DOJ also challenges certain of Dr. Bradford's Medicaid opinions. Notably, the DOJ does not challenge Dr. Bradford's use of the Medicaid claims data, the underlying validity of the data, or his methodology. Nor do they seek to exclude his error rates for Dr. Duggan or his analyses which demonstrate the payment bases taken from actual claims data. Instead, the DOJ focuses on certain narrow paragraphs which are taken out of context from the report as a whole. As discussed in more depth below, these opinions are the proper purview of expert opinion testimony and therefore should be permitted at trial.

A. Dr. Bradford's Opinions Regarding the Use of Generics Are Relevant, Reliable, and Admissible

The Court should not exclude Dr. Bradford's opinions regarding generic substitution based on the DOJ's mischaracterization Dr. Bradford's opinions set forth in paragraphs 22-26 and 31-35 of Dr. Bradford's expert report. (DOJ Motion at 13). Paragraphs 22-26 contain Dr. Bradford's opinion on brand to generic utilization. In this section of his report, Dr. Bradford provides background information on the generic market, including mention of the Hatch-Waxman act, based on his unchallenged expertise as a health care economist and his understanding of the generic market. Dr. Bradford begins with opinions on how innovator drugs and generic drugs get to market, and these opinions have not been challenged by the DOJ. (Bradford Rpt. at ¶¶ 19-21). Then Dr. Bradford turns to background analysis regarding brand to generic utilization under the Hatch-Waxman act. This part of his testimony, which is challenged by the DOJ, provides a necessary context and framework to help the lay jury. It does not invade the province of the judge or the jury but is rather is designed to assist the jury in understanding the complex area of generic drugs and the framework in which Dey operated. Furthermore, it may be noted that this Court has previously permitted testimony from an expert who discussed

generic markets and the Hatch-Waxman Act. (*See* Reid Decl. Ex. 2 at 20:13-19). Nor has the DOJ challenged the subsequent paragraphs, which contain Dr. Bradford's discussion of the economic and other literature which find that generic entry lowers prices. (Bradford Rpt. at ¶¶ 27-30).

In paragraphs 31-35, Dr. Bradford presents his opinions on generics and the concept of spread in the context of generics. After arguing that Dr. Bradford's analysis on generic utilization is improper because it is a legal opinion, in the next breath, the DOJ argues that Dr. Bradford's opinions on generic margins are improper because he has no legal foundation. Using his economic experience in studying the generic market, Dr. Bradford reaches an economic opinion that, as a mathematical consequence, "percentage margins for generic drugs will generally be higher than those on brand-name drugs." (Bradford Rpt. at ¶ 33). This mathematical observation regarding the relative cost of generic to brand products is based on Dr. Bradford's expertise in the area of generic drugs, an area which is outside the purview of the average juror. The critiques leveled by the DOJ are the types of questions properly raised on cross-examination so that the jury can itself decide what weight to give the testimony. *See*, *e.g.*, *Ruiz-Troche*, 161 F3d at 85. It is not a reason to exclude the very type of testimony Dr. Hartman provided for brand drugs in the MDL case just because we are now in the world of generics which is a very different world in terms of price competition.

B. Dr. Bradford's Opinions Regarding Medicaid Cross-Subsidization Are Relevant, Reliable, and Admissible

The Court should not exclude Dr. Bradford's Medicaid cross-subsidization opinions because these opinions are relevant to the jury's understanding of the central issues in this case and because they are reliable. Plaintiffs' expert, Dr. Duggan, calculates but for AWP's based on 125 percent of the pharmacy average indirect price that he calculates from the Dey transactional

data. These become his "average prices". The validity of Dr. Duggan's "damage" calculations rests on Dr. Duggan's assumption that Medicaid and Medicare would have paid his lower calculated average prices for the Dey subject drugs. As the DOJ states in their brief, it is their position that "a proper damages analysis in this case must determine what Medicare and Medicaid *would have paid.*" (DOJ Brief at 15 (emphasis added)). These particular opinions that the DOJ seeks to exclude from Dr. Bradford's report are those very opinions which challenge the assumption that Medicaid agencies would have paid the prices calculated by Dr. Duggan for the Dey drugs.

Dr. Bradford, after reviewing the voluminous evidence and data, and after drawing from his economic experience and background, opines that the prices set forth by Dr. Duggan do not cover a sufficient number of pharmacies such that access for Medicaid beneficiaries would be maintained at appropriate levels. These opinions are therefore highly relevant and will assist the jury at trial. This Court has already acknowledged that evidence of cross-subsidization is relevant. *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 32, 38 (D. Mass. 2007) ("At trial, there was no evidence about the extent of a shortfall in the costs of administration of the drugs in question in this litigation.") The Court has also specifically inquired about extent of cross-subsidization when it asked, "[b]ut no one's [provided] me the actual dollars and cents about what it would take to cross-subsidize for the real cost of dispensing. Is it the 1,000 percent spread you're talking about, or would it be a 200 percent spread?" (October 20, 2009 Hearing Tr. at 69:11-15).

State Medicaid programs are subject to an access requirement that requires that "[t]he agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general

population." 42 C.F.R. § 447.204 (2009). Dr. Bradford reviews the available economic data to analyze and quantify the access requirement. A legislature can mandate generic substitution, but no law requires a provider to participate in the Medicaid program, and Dr. Bradford's opinion points out the economic reality that no rational provider will participate in any program if it does not have an economic incentive to do so. Dr. Duggan does not consider the dispensing fee at all in his calculations, but instead opines that Medicaid agencies would have used his lower average prices in their reimbursement formulas while maintaining constant dispensing fees and without affecting access. Dr. Bradford, on the other hand, does not assume that Medicaid programs would have been able to continue to maintain access at the lower prices proposed by Dr. Duggan, and examines the data in several ways in order to quantify the access requirement. He does not, however, opine that states should pay at certain levels, but is instead offering opinions on the how the economics of reimbursement would change were Dr. Duggan's average prices used for reimbursement.

Dr. Bradford examines the payments to the marginal pharmacy, or the pharmacies that are paying the highest cost for drugs. The opinions and analyses contained on pages 45-46, 48-49, and 126 of Dr. Bradford's report are highly relevant and well founded. The DOJ argues that this marginal pharmacy analysis is legally flawed and should be excluded, stating that prices at or above the 95th percentile are not prices "generally" paid. (DOJ Brief at 15). What the DOJ fails to note is that its own expert, Dr. Duggan, calculated and examined the 95 percentile price. (*See* Duggan Rpt., Dkt. 6184 at Ex. 270 at p. 36).[10] Other experts, including a DOJ expert, have given opinions regarding the meaning of "generally" paid, and have found that the average percentile as used by Dr. Duggan is not sufficient. For example, during his deposition, the

[10] Dr. Duggan testified that he examined the 95% percentile because, unlike averages, it reveals the heterogeneity across customers in the price. (Duggan 7/15/08 Dep. at 451:19-416:8).

DOJ's own expert, Dr. Schondelmeyer, testified that the use of an average price "is not a good reimbursement policy for anybody." (*See* Schondelmeyer 2/26/09 Dep. at 696:14-15, Reid Decl. Ex. 4). Dr. Bradford is not offering any opinion on federal law but rather is offering an economic analysis that is necessary for the jury to determine whether the Medicaid system would have sufficient providers in Dr. Duggan's but-for world. Furthermore, the DOJ's criticism of the Adams and Kreling study is misplaced because it supports Dr. Bradford's opinions regarding the prevalence of a cross-subsidy between ingredient and dispensing cost payments: "… it appears across the states relatively low payments for dispensing fees are balanced by relatively high payments for ingredient cost." (Dkt. 6194, Ex. 13 at p. 41).[11]

The DOJ puts forward another criticism of Dr. Bradford's "marginal pharmacy" analysis by appealing to a declaration by Dr. Duggan (DOJ brief at 18, 19), where he claims that lower payments for generic drugs would be more than offset by higher payments for brand drugs in his arbitrary 125% average price but-for world.[12] Apparently it is the DOJ and Dr. Duggan's position that the solution to Dr. Duggan's postulating average prices no economically rational pharmacy would accept is to switch Medicaid patients to higher-priced brands. In making this argument, they demonstrate that the natural economic consequences of Dr. Duggan's average pricing is the decrease in the usage of lower-priced generics in the Medicaid program, hardly a desirable result. But even taking Dr. Duggan's assumptions that higher brand prices would result

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[11] Moreover, Plaintiff's expert Dr. Duggan, in performing his damage calculations, also ignores the authors' admonition that states "may want to better align payments with each component cost (ingredient and dispensing) before considering restructuring of payment methods." Dr. Duggan merely attempts to align the payment level for the drug component of payment without considering the underpayment on dispensing costs.

[12] In this instance, despite having critiqued Dr. Bradford for his accounting of a well-known offset involving dispensing fees, Plaintiffs appear to be appealing to another offset of their own creation to defend the lowered payments implied by their damage calculations.

from and compensate for his prices, it is unclear how arbitrarily raising imagined payments to pharmacies for brand drugs as an offset for reductions in generic drug payments can be considered in isolation from his damage calculations. Pharmacies either received too much money or they did not. Put simply, applying Dr. Duggan's but-for payment methodology to all drugs will result in one of three outcomes: overall payments that are either lower than, equal to, or higher than the actual payments. If using his methodology raises overall payments to pharmacies or leaves them unchanged then one can conclude that there were no overpayments for drugs overall. However, if his methodology lowers overall payments to pharmacies then the losses potentially incurred by "marginal" pharmacies become a relevant question. On this point, another of Plaintiffs' experts, Dr. Schondelmeyer, has opposed lowering of overall payments because of the low margins experienced by independent pharmacies. (*See* Schondelmeyer CA Report, Reid Decl. Ex. 5). Thus, the examination of overall payments suggested by Dr. Duggan would either produce no damages or would lead to a result apparently opposed by Dr. Schondelmeyer, namely the elimination of providers from Medicaid. Hence Dr. Duggan's criticism of Dr. Bradford's "marginal pharmacy" analysis reveals the inconsistencies in Plaintiffs' damages theory and not the other way around.

The DOJ also sets up another straw man argument by critiquing Dr. Bradford's use of wholesaler data, claiming that it is not an available price that could have been used by Medicaid agencies for reimbursement.[13] Dr. Bradford is not advocating that the wholesaler data be used for reimbursement, but is analyzing it to show the prices generally paid in the marketplace as a means of testing Dr. Duggan's assertion that calculations would be accepted. The wholesaler

[13] Since Dey has nothing to do with a state setting a reimbursement policy, setting SMAC, or defining a usual and customary charge, it is difficult to see why Dey's access to wholesaler data would be at issue.

data is the best source for measuring the actual prices paid to wholesalers. The DOJ agrees the McKesson data is reliable. Furthermore, despite the DOJ's protestations to the contrary, the Cardinal wholesaler data is also reliable. The DOJ has not pointed to any quantitative information to support their claim that the data "overstates provider acquisition costs." A comparison of McKesson prices, which are unchallenged, and the Cardinal prices show that they are comparable. (See Bradford Decl. at ¶ 4). Furthermore, the DOJ relies on testimony of Cardinal's 30(b)(6) witness regarding the sale and purchase of brand products. (*See* 9/9/08 Warren Dep at 244, Reid Decl. Ex. 6). In any event, this is all a matter of cross-examination, not a pretrial motion.

Dr. Bradford also presents opinions on the dispensing fee shortfall, contained on pages 53-60, 130-131, 134, and Appendix G to his report, which are comprehensive and reliable. Dr. Bradford examines numerous dispensing cost studies and other state evidence and opines on the adequacy of payment levels over time. This is admissible and relevant evidence that once again goes to the core of the Court's questioning on dispensing fee shortfalls. The DOJ should not be allowed to on one hand argue that Dr. Bradford's opinions and analysis about dispensing costs should not be heard because those are disputed issues for the jury (DOJ Brief at 20) while at the same time pointing to their expert, Dr. Duggan's, opinion regarding states' payment methodologies and ingredient cost payments. (DOJ Brief at 22). Dr. Bradford's dispensing fee analysis is not unsupported or speculative. While Dr. Duggan may be able to point to instances when a decrease in ingredient cost reimbursement was not accompanied by an increase in dispensing fees, in many other instances, the dispensing fee did increase. For example, in 2004, California decreased its ingredient cost reimbursement when it changed from an AWP minus 10% to AWP minus 17% methodology. At the same time, it increased the dispensing fee from

$4.05 to $7.25. (*See* Rosenstein 5/19/09 Dep. at 188:19-197:2, Reid Decl. Exhibit 7). In 1995, New York decreased its ingredient cost reimbursement from AWP to AWP minus 10%, and increased its dispensing fee from $2.60 to $4.50 for brands and $5.50 for generics. (*See* Mark-Richard Butt 1/26/10 Dep. at 199:7-202:5, Reid Decl. Exhibit 8). Dr. Bradford also points to the example of the Appellate Board Ruling relating to Arkansas for the factual reality that the dispensing fee was increased when ingredient cost reimbursement was reduced. Numerous other examples exist. This is relevant evidence, and is the same type of opinion given by Dr. Duggan. This is quintessentially the type of matter best left for cross-examination of both experts.

Finally, the DOJ attacks Dr. Bradford's dispensing fee shortfall and his Massachusetts Medicaid model. (DOJ brief at 22). However, the critique is misplaced. To be consistent with the Massachusetts benchmark on the ingredient side, Dr. Bradford applied the Massachusetts benchmark on the dispensing side as well. In fact, when Dr. Bradford performed the calculations using the dispensing fees from all of the states, the dispensing fee shortfall resulted in a virtually identical negative number overall.[14] (*See* Bradford Decl. at ¶ 5).

C. Dr. Bradford's Opinions Regarding Medicaid Payment Variations Are Relevant, Reliable, and Admissible

The DOJ also seeks to exclude several of Dr. Bradford's opinions regarding payment variation across states and his use of Massachusetts as a basis for alternative calculations. Specifically, the DOJ challenges paragraphs 93 (listed as p. 41), 169 180, 212, and 218 (listed as p. 103), as well as portions of appendix G. The DOJ has not challenged the remainder of Dr. Bradford's analysis which reviews payment variation on a state level. It is uncontroverted that states formulate their own reimbursement policies with a great deal of flexibility subject to

[14] All the data necessary to do such an analysis was contained in the supporting materials produced by Dr. Bradford along with his report, enabling Plaintiffs to perform such a calculation.

guidelines set by CMS. (*See*, *e.g.*, 10/02/2008 Reed Dep. 1373:14-17, Reid Decl. Ex. 9). In formulating their reimbursement methodologies, states make policy choices which result in some states paying more for drugs while others pay much less for those same drugs. Dr. Bradford has examined all of the claims-level state claims data available, as well as the aggregate SDUD and SMRF/MAX data for all fifty states, and is qualified and able to explain to the lay jury the different payment methodologies across states and the actual data which show how these methodologies enable some states, like Massachusetts, to pay less. For some of the time period at issue, Massachusetts based reimbursement on Dey's published, declining WAC. Dr. Bradford quantifies the difference in Dr. Duggan's damage calculations if all of the states had chosen to base reimbursement as Massachusetts did. The DOJ does not challenge the data relied on by Dr. Bradford or his methodology. Instead, they mischaracterize his opinion as one in which he concludes "that lawmakers did not really intend to pay estimated acquisition cost and instead chose to pay Dey's falsely inflated AWPs." (DOJ Brief at 24). This mischaracterization obfuscates Dr. Bradford's point. Dr. Bradford opines that "[i]n my opinion, a low paying state establishes a payment threshold that was available to all states. As a result all payments above that threshold can be viewed as choices made by the individual states." (Bradford Rpt. at ¶ 169). This opinion relates, among other things, to Dey's scienter, one of the elements of the False Claims Act. Dey reported a flat AWP and a declining WAC throughout the entire time period at issue, and the choice of one state to base reimbursement on the higher flat AWP while others based reimbursement on the lower, declining WAC cannot be attributed to any intent on Dey's part, nor can Dey be held to have caused such higher payment. Finally, the state payment variation is also necessary in order to understand the flaws in Dr. Duggan's Medicaid

extrapolation, in which the differences in states are simply assumed away in a way which leads to inflated damage claims.

CONCLUSION

For the reasons set forth herein, this Court should deny the United States' Motion to Exclude Certain Opinions of W. David Bradford, Ph.D.

Dated: March 17, 2010

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on March 17, 2010, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Sarah L. Reid
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